REMARKS

This paper contains a supplemental amendment responsive to the Official Action dated January 18, 2007, and following a personal interview with the examiner, which is summarized herein. In view of the amendments submitted herewith and the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

Status of the prosecution.

A final rejection of claims 163-174 was issued in the January 18, 2007 Office Action. All claims remain rejected on the grounds of nonstatutory double patenting as allegedly unpatentable over claims 1-34 of U.S. Patent 7,045,145. The Action acknowledged Applicant's intention to file a terminal disclaimer upon determination of allowable subject matter.

Claims 163-166 and 171-174 remain rejected under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. 5,762,956 (the 956 patent) in view of U.S. 5,023,084 (the 084 patent).

Claims 167-170 remain rejected under 35 U.S.C. §103(a) as allegedly unpatentable over the 956 patent in view of the 084 patent, and further in view of U.S. 6,007,835 (the 835 patent).

On May 11, 2007, Applicant filed a Request for Continued Examination, accompanied by a reply to the January 18, 2007 Office Action. No claim amendments were submitted with that reply.

On July 23, 2007, the examiner conducted a personal interview with Applicant's undersigned attorney and Dr. Thomas Rossi, Chief Executive Officer of Agile Therapeutics, Inc., the assignee of the present application. Applicant's attorney thanks the examiner for the interview, which is summarized below.

Interview summary.

The rejection under 35 U.S.C. §103(a), in view of the 956 patent and the 084 patent, was discussed. The general unpredictability of the art was discussed. Elements of the 956 patent that teach away from the claimed invention were highlighted by Applicant's representatives. These included: (1) the "consisting of" and "unique combination" language, which teach against adding anything to the disclosed enhancer combination, and (2) the

teaching of 30-60% by weight of the enhancer combination. An amendment to the current claims, limiting the total enhancer amount to 30% or less, and possibly including amounts of the remainder of the adhesive polymer matrix, was discussed.

Elements of the 084 patent that would lead the skilled artisan away from trying the enhancers disclosed therein were also discussed. These included, among others, (1) the teaching that a high concentration of the 084 patent's preferred enhancers would be detrimental to skin adhesion, and so would not be combined with the already-large amount of enhancers taught by the 956 patent, and (2) the substantial difference between the multi-compartment system of the 084 patent, in which the progestin and estrogen hormones are contained in different compartments, and the system of the present invention, in which the hormones and enhancers are disposed together in one adhesive polymer matrix. A claim amendment specifying this distinction, i.e., pointing out that the hormones of the present invention are present in a single adhesive polymer matrix, was discussed.

The possibility of Applicant submitting additional objective evidence of unexpected results, namely experimental data showing such results from transdermal delivery systems outside the exemplified formulation, was also discussed.

Current amendments to the specification and claims.

The specification has been amended to correct a typographical error in paragraph 0043. Claims 163 has been amended and new claims 176-180, which depend from claim 163, have been added. Claim 163 has been amended to more clearly recite a transdermal delivery system comprising a backing layer and an adhesive polymer matrix containing progestin and estrogen hormones, wherein both the estrogen and the progestin are disposed together within the matrix, rather than being separated into multiple compartments. Support for this claim amendment is found throughout the specification, e.g., at paragraphs 0014, 0015 and 0057, among others, and in Examples 1 and 2.

Claim 163 has also been amended to specify that the combination of the four skin permeation enhancers is present within the adhesive polymer matrix in an amount up to 30% by weight of the adhesive polymer matrix. Dependent claims 176-180 recite more specific limitations on the amount of the enhancer combination present in the adhesive polymer matrix, or utilized to formulate the adhesive polymer matrix. Support for these claim

amendments and new claims may be found throughout the specification, e.g., at paragraphs 0054 and 0065, among others.

In the aforementioned interview, the examiner suggested that amounts of the other ingredients in the adhesive polymer matrix also be specified in the claim. However, after further consideration, Applicant submits that such recitation is not needed to distinguish the claimed invention over the cited prior art, as discussed in greater detail below, so the claim was not amended in that manner.

No new matter has been added by way of the claim amendments. For the reasons set forth below, Applicant submits that the claims are in condition for allowance.

The claimed subject matter is not obvious in view of the cited prior art.

Claims 163-166 and 171-174 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. 5,762,956 (the 956 patent) in view of U.S. 5,023,084 (the 084 patent). According to the Office Action, the 084 patent teaches a transdermal estrogen/progesterone dosage unit comprising an adhesive matrix with permeation enhancers, wherein capric acid is a preferred enhancing agent because it provides "highly satisfactory skin absorption enhancement." The Office Action alleges that, for this reason, the skilled artisan would have been motivated to modify the three-enhancer-containing transdermal delivery device taught by the 956 patent by the addition of capric acid as a fourth skin permeation enhancer, with a reasonable expectation of having a transdermal delivery device with highly satisfactory skin absorption enhancement for the combination of estrogen and progesterone. Applicant continues to traverse this rejection.

The 956 patent teaches away from adding *anything* to the enhancer combination disclosed therein. Through its repeated use of the term "consisting of," and "unique combination," the 956 patent teaches that its three enhancer system is not amenable to alteration or supplementation. Furthermore, the 956 patent teaches that the enhancer combination must be present in its system in an amount between 30 and 60% by weight of the adhesive polymer matrix, with preferred embodiments including 35-55%, 45% and 50-60% (956 patent, col. 3, lines 39-41, col. 7, lines 57-59, col. 9, table at lines 1-10).

In contrast, the transdermal delivery system of the present invention specifies a combination of four skin permeation enhancers, clearly taught against by the 956 patent, in an

amount that does not exceed 30% by weight of the adhesive polymer matrix. The teachings of the 956 patent provide no suggestion to modify the system disclosed therein to arrive at the invention as presently claimed.

The 084 patent does not supply the requisite teachings that are absent from the 956 patent. The 084 patent teaches capric acid as a preferred skin permeation enhancer for certain progestins and estrogens. However, the 084 patent teaches use of capric acid for delivery of hormones from a multi-compartment device in which the estrogen is present in one compartment and the progestin and enhancers are present in a different compartment. In contrast, the transdermal delivery system of the present application is one in which the progestin and estrogen hormones, along with the skin permeation enhancers, are present together in the adhesive polymer matrix, rather than being separated into two or more compartments. There is nothing in the 084 patent to suggest to the skilled artisan that capric acid would be a useful skin permeation enhancer for delivery of progestins and estrogens from such a system. This is especially the case in view of the unpredictability in the art of transdermal hormone delivery, which has been thoroughly argued, with supporting evidence, in Applicant's responses to previous Office Actions.

Hence, there is no rational basis taken from either the 084 or the 956 patent, or the combination of those teachings, to impart to the skilled artisan any reason for adding capric acid to the system of the 956 patent, or to substantially reduce the total amount of enhancers in the system, to produce the presently claimed transdermal delivery system. Accordingly, the presently claimed system cannot be said to be obvious in view of the teachings of those two patents.

Claims 167-170 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over the 956 patent in view of the 084 patent, and further in view of U.S. 6,007,835 (the 835 patent). Applicant continues to traverse this rejection. The addition of the 835 patent to support the rejection of claims 167-170 is also untenable in view of the absence of teaching in the 956 patent and the 084 patent of the invention as currently claimed. The 835 patent's purported teaching of PVP/VA-S30 do not supply a reason to combine the teachings of the cited references so notably absent from the primary references.

In summary, Applicant has presented reasoning and evidence, in this paper and in previous replies, to support his assertion that the invention as presently claimed is not

obvious over the cited references. Applicant therefore requests reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a).

Non-statutory double patenting.

All claims remain rejected on the grounds of nonstatutory double patenting as allegedly unpatentable over claims 1-34 of U.S. Patent 7,045,145. Applicant reiterates his intention to file a terminal disclaimer upon determination of allowable subject matter.

Conclusion.

In view of the amendments submitted herewith and the foregoing remarks, the presently pending claims are believed to be in condition for allowance. Applicant respectfully requests early and favorable reconsideration and withdrawal of the rejections set forth in the January 18, 2007 Official Action, and allowance of this application.

Respectfully submitted,

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